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THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 11

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MAILED

Ex parte MARGARET E. APPLEYARD
and BRENDAN McDONALD

OCT 11 1995

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 94-0359
Application 07/531,613¹

ON BRIEF

Before WINTERS, DOWNEY, and WILLIAM F. SMITH, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision refusing to allow claims 1 through 6, which are all of the claims in the application.

¹ Application for patent filed June 1, 1990.

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THE INVENTION

Appellants' invention relates to a method for detecting or diagnosing senile dementia of the Alzheimer type (Alzheimer's disease) by measuring acetylcholinesterase (AChE) activity in the ocular fluids of a patient, and determining if such AChE activity is elevated over that found in the ocular fluids of individuals who do not have Alzheimer's disease.

Claim 1 is illustrative of the subject matter on appeal:

1. A method for detecting Alzheimer's disease, which comprises measuring the level of acetylcholinesterase activity in ocular fluids of a patient, and determining if such level of acetylcholinesterase (AChE) activity is above the average level of acetylcholinesterase activity found in ocular fluids in normal controls.

THE REFERENCES

The references relied on by the examiner are:

Andrew deRoetth, Jr., M.D. (deRoetth), "Cholinesterase Activity In Ocular Tissues And Fluids", 43 Arch. Ophthalmol. 1004-1025 (1950).

Barbara Chipperfield et al. (Chipperfield), "Plasma Cholinesterase Activities In Dementias, Depressions And Schizophrenia", 2 International Journal of Geriatric Psychiatry 247-254 (1987).

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John R. Atack, PhD et al. (Atack), "Cerebrospinal Fluid Cholinesterases in Aging and in Dementia of the Alzheimer Type", 23 Ann. Neurol. 161-167 (1988).

Yasumasa Yamamoto et al. (Yamamoto), "Plasma and serum G4 isoenzyme of acetylcholinesterase in patients with Alzheimer-type dementia and vascular dementia", 27 Ann. Clin. Biochem. 321-326 (1990).

THE ISSUES

The issues presented for review are:

(1) Whether the examiner correctly rejected claims 1 through 6 under 35 U.S.C. § 103 as unpatentable over Chipperfield, Atack, or Yamamoto, either of those "primary" references taken in view of deRoethth; (2) whether the examiner correctly rejected claims 1 through 6 under 35 U.S.C. § 112, second paragraph, as indefinite; and (3) whether the examiner correctly rejected claims 1 through 6 under 35 U.S.C. § 112, first paragraph, as based on a nonenabling disclosure.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) The instant specification, including Figures 1, 2, and 3, and all of

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the claims on appeal; (2) appellants' brief before the board; (3) the draft manuscript attached to Paper No. 6, referred to at page 6 of the brief, and the literature articles referred to at page 8 of the brief; (4) the examiner's answer; and (5) the prior art references cited and relied on by the examiner.

On consideration of the record, including the above-listed materials, we reverse each of the examiner's rejections. Our reasoning is set forth below.

DISCUSSION

The examiner's position to the contrary, notwithstanding, we hold that the subject matter sought to be patented in claims 1 through 6 would not have been obvious at the time the invention was made to a person having ordinary skill in the art based on the cited references of record. We also hold that claims 1 through 6 define appellants' invention with a reasonable degree of precision and clarity, and that claims 1 through 6 are based on a fully enabling disclosure. The examiner, we believe, has not established a prima facie case of obviousness, indefiniteness, or lack of enablement, essentially

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for reasons stated in appellants' brief before the board, pages 4 through 16. With one exception noted infra, we shall adopt those reasons as our own. We add the following comments for emphasis only.

The combined disclosures of prior art references, regardless how viewed, do not provide any teaching or suggestion that the level of acetylcholinesterase activity in ocular fluids of a patient may be used as a biological marker for Alzheimer's disease. We find no suggestion stemming from the prior art that the level of acetylcholinesterase activity in ocular fluids of a patient having Alzheimer's disease is significantly different from or higher than the average level of acetylcholinesterase activity found in ocular fluids in normal controls. A fortiori, we find no teaching or suggestion that any relative difference in the level of acetylcholinesterase activity in ocular fluids would be significant or would be useful as a biological marker.

On this record, the examiner has not established a prima facie case of obviousness of claims 1 through 6 under 35 U.S.C. § 103. Furthermore, in section (11) of the answer entitled "Response to argument", the examiner does not address appellants' arguments respecting the prior art rejection. See

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particularly page 8 of the answer, where the examiner restates the rejection presented earlier at pages 5 through 7 but does not respond to appellants' arguments on appeal.

The examiner asserts that claims 1 through 6 are indefinite in view of the recitations of "above the average level", "average level", and "a significant number". We agree with appellants, however, that this rejection is untenable. Giving the claim language its plain meaning, when read in light of the specification, we find that the criticized terms define appellants' invention with a reasonable degree of precision and particularity. Again, we observe that the examiner does not present a substantive answer or response to the arguments presented in appellants' brief respecting the rejection under 35 U.S.C. § 112, second paragraph. See the examiner's answer, page 8.

As best understood from a review of the answer in its entirety, we find that the examiner does not challenge the protocol or data in appellants' working example carried out at post-mortem. See Example 2 in the specification. Apparently, the examiner accepts the data as establishing statistically significant differences between the acetylcholinesterase content of ocular fluid from patients with histologically diagnosed Alzheimer's disease vis-a-vis normal aged controls.

Having accepted those post-mortem results, the examiner carries the burden, we believe, of providing adequate reasons explaining why appellants' research would not reasonably be expected to hold true for living patients. This, the examiner has not done. As set forth in the instant specification, pages 10, 13, and 14, the presence of acetylcholinesterase in ocular fluid is unlikely to be a post-mortem artefact. The examiner offers no reasons or evidence controverting that fact, nor the fair inference that it is valid to extrapolate the specification results obtained at post-mortem to living patients.

To the extent that the examiner criticizes appellants' data on the ground that all patients were not standardized with respect to various factors (answer, page 4), we find, with one exception, that the criticism is unsupported. The exception relates to the "drug regimes of the patients" which, according to appellants, could decrease secretion of acetylcholinesterase from cholinergic tissues of the eye. See the specification, paragraph bridging pages 10 and 11. Even taking that factor into account, however, we find that the examiner has not presented an analysis explaining why a person having ordinary skill in the art would have doubted the extrapolation of results obtained in Example 2 at post-mortem to living patients.

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The examiner's rejections under 35 U.S.C. § 103, 35
U.S.C. 112, second paragraph, and 35 U.S.C. § 112, first
paragraph, are reversed.

REVERSED

Sherman D Winters

SHERMAN D. WINTERS)
Administrative Patent Judge)

Mary F Downey

MARY F. DOWNEY)
Administrative Patent Judge)

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William F Smith

WILLIAM F. SMITH)
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